

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

<p>IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION</p>	
<p>THIS DOCUMENT RELATES TO:</p> <p><i>The City of New York v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 04-CV-06054</p> <p><i>County of Albany v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0425</p> <p><i>County of Allegany v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0236</p> <p><i>County of Broome v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0456</p> <p><i>County of Cattaraugus v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0256</p> <p><i>County of Cayuga v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0423</p> <p><i>County of Chautauqua v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0214</p> <p><i>County of Chemung v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-6744</p> <p><i>County of Chenango v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0354</p> <p><i>County of Columbia v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0867</p> <p><i>County of Cortland v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0881</p> <p><i>County of Dutchess v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 05-CV-6458</p> <p><i>County of Essex v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0878</p> <p><i>County of Fulton v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0519</p>	<p>MDL NO. 1456 Civil Action No. 01-12257-PBS</p> <p>Judge Patti B. Saris</p> <p>PLAINTIFFS' JOINT SURREPLY IN FURTHER OPPOSITION TO DEFENDANT AMGEN INC'S INDIVIDUAL MOTION TO DISMISS</p>

County of Genesee v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-00267

County of Greene v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0474

County of Herkimer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00415

County of Jefferson v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0715

County of Lewis v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0839

County of Madison v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00714

County of Monroe v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6148

County of Nassau v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 04-CV-05126

County of Niagara v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06296

County of Oneida v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0489

County of Onondaga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0088

County of Ontario v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6373

County of Orleans v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6371

County of Putnam v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 05-CV-04740

County of Rensselaer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00422

County of Rockland v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-7055

County of Schuyler v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6387

County of Seneca v. Abbott Laboratories, Inc., et al.

W.D.N.Y. Case No. 05-CV-6370

County of St. Lawrence v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0479

County of Saratoga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0478

County of Steuben v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6223

County of Suffolk v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 03-CV-12257

County of Tompkins v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0397

County of Ulster v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 06-CV-0123

County of Warren v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0468

County of Washington v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0408

County of Wayne v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06138

County of Westchester v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-6178

County of Wyoming v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6379

County of Yates v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06172

Amgen, in its reply memorandum (“Amgen Reply”), reinforces its admission that drugs described as “physician administered” can be and are reimbursed based on AWP. *See* Amgen Reply at 2; *see also* Amgen MTD¹ at fn 6. By doing so, Amgen bolsters the irrelevance of the “physician administered” label to plaintiffs’ claims and illustrates that Amgen’s motion is, in fact, much ado about nothing.

Despite its admission, Amgen nevertheless boldly asserts that all of plaintiffs’ claims related to “physician administered” drugs should be dismissed because: (i) they were reimbursed at “actual cost”; (ii) there is not an adequate basis for calculating the spread based on plaintiffs’ market prices; and (iii) it would be convenient for Amgen to have the case so narrowed.

Amgen’s own admissions regarding “physician administered” drug reimbursement make clear why its request for dismissal fails entirely.

Moreover, as shown in great detail in their opposition to the Amgen’s individual motion to dismiss (“Amgen Opp.”), plaintiffs plead facts in support of their Best Price and AWP fraud claims with sufficient specificity to meet the requirements of Fed. R. Civ. P. 9(b) as well as this Court’s prior rulings in *Suffolk*. *See* Amgen Opp at 2-4. Plaintiffs’ opposition to Amgen’s motion is not disturbed in the least by Amgen’s Reply, to wit:

First, the phrase “physician administered” has no operative or controlling significance in terms of reimbursement under New York Medicaid or whether such reimbursement is based on AWP. The Statute provides that New York Medicaid reimburses “for drugs provided by medical practitioners and claimed separately by the practitioners, [at] the actual cost of the drugs to the practitioners.” N.Y. Soc. Serv. Law §367-a(9) (emphasis added). Thus, in order for a physician

¹For clarity and consistency, plaintiffs use the same definitions of all terms and cases cited in their corresponding individual opposition memorandum (“Amgen Opp.”). Additionally, all other causes not addressed herein are addressed in Plaintiffs’ Consolidated Sur-Reply to Defendants Motion to Dismiss, filed contemporaneously herewith (referred to herein as “Consolidated Sur-Reply.”)

administered (or any other) drug to be reimbursed at “actual cost”, the “medical practitioner” must: (i) provide the drug; and, (ii) claim reimbursement separately. *See id.* Plaintiffs concede that the plain meaning of the statute says that drugs so provided and claimed are reimbursed based on actual cost. All other drugs are reimbursed based on AWP and properly part of plaintiffs’ case.

Second, plaintiffs’ claims are based on reimbursements paid to health care providers pursuant to the drug NDC and corresponding AWP. Any distinction based on “physician administered” is irrelevant. A large portion of these drugs are also frequently referred to as “specialty pharmacy” products. Expert Report of Prof. Berndt (“Berndt Report”)² at ¶ 90.

Third, “physician administered” drugs are not the exclusive bailiwick of medical practitioners. Health care providers such as specialty pharmacies, home health services, nursing homes and in-house hospital pharmacies, all of which may and do seek reimbursement based on AWP, are equally incentivized by spread. Specialty “pharmacies may provide the drug to physicians, but then receive reimbursement directly from the health plan/insurer, thereby eliminating the physician reselling transaction.” Berndt Expert Report at ¶ 99; *see also* ¶ 103. Any health care provider with a DEA number may seek reimbursement for so called “physician administered” drugs without providing any associated services.

Fourth, the “physician administered” description has further been eroded by payors that also consider the drugs “self-administered”. For example, Aetna considers Amgen products Infergen, Kineret and Enbrel to also be self-administered.³

Fifth, plaintiffs do not seek recovery of damages based on expenditures pursuant to a medical practitioner providing drugs and seeking actual cost reimbursement. New York Medicaid

²By citing the Berndt Report, plaintiffs in no way subscribe to its findings *in toto*. This Court commissioned Prof. Berndt for guidance in AWP matters, as such plaintiffs direct the Court to the findings relevant to the issues at hand.

³*See* http://www.aetna.com/formulary/inject_2006.html.

reimburses a medical practitioner at actual cost because the medical practitioner will also seek reimbursement for the physician visit and related services. Similar to Medicare Part B, New York Medicaid reimburses such situations based on J-Codes, not NDC.

Sixth, Amgen does not dispute -- nor can it -- that prior to June 9, 1994 New York Medicaid reimbursed all Amgen drugs to all claimants based on AWP, irrespective of any "physician administered" description. *See* Amgen Reply at 2.

Seventh, Amgen provides no reasoning or basis for why actual wholesale market prices offered to Ven-a-Care of the Florida Keys, Inc. ("Ven-a-Care"), a licensed pharmacy, and available on a nationwide basis to similar pharmacies participating in the McKesson/Servall program are invalid as a conservative and true AWP proxy. Amgen merely states its voluntary dismissal from the California action precluded it from having an opportunity to protest those prices there. *See* Amgen Reply at fn 2. Given that no remaining defendant in that matter challenged the legitimacy and source of these prices for calculating spread, any protest by Amgen there would be similar to its protest here, a red herring.

Eighth, plaintiffs' allegations of Amgen's admitted "drug revenue model", which is based on Amgen's ability to create whatever spread it likes for its drugs, combined with examples of fraudulent spread for Aranesp, Neutasta and Neopogen establish a reasonable inference of a company-wide AWP fraud scheme that implicates Epogen, Infergen, Kineret and Enbrel (*see* CC ¶¶ 223-235; NSAC ¶¶ 210-234), and satisfies the requirements of Fed. R. Civ. P. 9(b).⁴ *See U.S. ex rel Franklin v. Parke Davis*, 147 F.Supp.2d 39, 46 (D. Mass. 2001).

Ninth, there is no legal basis under Fed. R. Civ. P. 8(a) or 9(b) for the dismissal of valid claims in order to "reduce the burden and expense of discovery" on Amgen. *See* Amgen Reply at 3.

⁴That said, per CMO #21, in February, 2006, Amgen produced discovery to plaintiffs for the first time. This discovery will permit plaintiffs to provide even greater specificity of Amgen's company wide scheme should the Court require it.

CONCLUSION

For all reasons set forth herein and in plaintiffs' opposition memorandum, Amgen's individual motion to dismiss should be denied in its entirety.

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Respectfully submitted,

**City of New York and all captioned Counties
except Nassau, by**

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